



THE REGULATOR

FOR THE WELL INFORMED LABORATORY



Volume 1, Issue 1

May, 2002

Diagnostic Services Unit Launches Newsletter

At last, we have been brought kicking and screaming into the world of e-mail and internet. New software has helped us creatively challenged folks set up and publish a newsletter. This type of task should be left to the retired; nevertheless, we are undaunted in our efforts to keep our licensed labs well informed. Our goal is to publish The Regulator on a quarterly basis. Your input would be appreciated.

Let us know what information you would like to see in future issues.

This newsletter would not be possible without the enthusiasm, support and encouragement of the Health Care Section Director, Carol Zafiratos.

Future articles will include Point of Care Testing and the Georgia POC Network, Bioterrorism, noninvasive testing, CPT coding

and facility profiles. We will also introduce the Advisory Council members one by one.

FYI

The Office of Regulatory Services is providing this newsletter **free** to all licensed labs that provide us with an e-mail address. Those labs without e-mail access please contact our office.

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Special points of interest:

- ? The amending of the regulations was five years in the making.
- ? Retirement News.
- ? Dangerous Mail.
- ? So many laws, so little notifying.

From the director...Marty Rotter

When someone thinks of regulation there is usually an association to enforcement and possible fines or worse. Those are components of the regulatory process, but they are not the only parts. A former administrator with CMS once said that regulation

should be an open book test. This means that everyone should know what a regulator would look for and there should be no surprises. However, I also believe that a good regulatory system provides information to those who are regulated to assist in meeting and understand-

ing rules and regulations. Unfortunately because of limited resources, ORS has not been able to do as much education as we would like. The inauguration of this newsletter is one way we can effectively give you pertinent information about regulatory issues and general information that will be helpful in running your laboratory. We are excited about the newsletter and hope, in the issues to come, you find articles that you can use as we work together to provide quality laboratory services for our state.

Biological Packaging May Be Hazardous to Your Health

It has been reported to the Department that many biological products are being shipped to labs improperly packaged. One facility reported that the mailroom called infection control because they had a crushed package that was dripping blood. This is a dangerous practice and can be hazardous to the health and safety of anyone who must handle the packages.

The United States Department of Transportation has extensive regulations regarding the shipment of infectious materials. You may find the regulations at <http://hazmat.dot.gov>. The specific regulations

are §§49 CFR Parts 171-180. **Please note: There are stiff fines and other penalties for failure to meet packaging requirements.** So please:

- ? Wrap it up;
- ? Identify It;
- ? Ship it appropriately.



Be careful out there!

It is a short leap to another subject called:

BIOTERRORISM

Does your lab have a disaster or BT Plan to cover suspected

anthrax patients, test specimens considered biohazardous or who to call for instructions? The State Public Health Lab in Decatur can help you to formulate a plan and provide handling instructions. If you have an urgent need to contact them, the general number is 404-327-7900. We will work closely with Public Health and Dr. Elizabeth Franko on articles of interest in future issues.

Are You violating the Law?

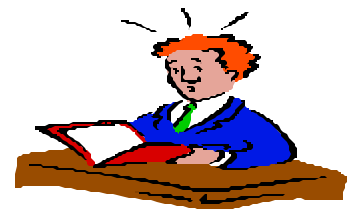
The Official Code of Georgia [O.C.G.A.] § 43-34-31.1[a] is a part of the Medical Practices Act. The statute says that a person that is physically located in another state and who performs an act that is part of patient care services located in Georgia, must have a license to practice medicine in Georgia. This includes examination

of pathological material that would affect the diagnosis or treatment of the patient. Those of you who use out-of-state reference labs should be aware of and inform your reference lab of this

law. Any inquiries should be addressed to the Georgia Composite Board of Medical Examiners. The tele-

"Any such out-of-state or foreign practitioner shall not have ultimate authority over the primary diagnosis of citizens."

phone number is 404-656-3913. The e-mail address is: medbd@dch.state.ga.us.



Laboratory personnel shortage

The nationwide laboratory personnel shortage has hit Georgia. There are a number of medical technology programs that have closed. The average age of most medical technologists is approaching 45 years. The rural areas are feeling the pinch more so than the metro areas.

We have been asked whether the personnel regulations will change. All we can say is, not at this time. Maintaining

current standards is the prudent thing to do. The law describes the activities of technologists and technicians.

Some good news seems to be on the horizon. There is a group working with Lester Hardigree and other education med techs to create awareness of the profession among educators and high schoolers. The high school program looks promising. It should act as a springboard for recruiting more stu-

dents wanting to pursue AA and BS Medical Technology/Technician degrees. The profession needs exposure if it is to remain a viable career for younger generations.

More later.



New and amended lab regulations are now in effect

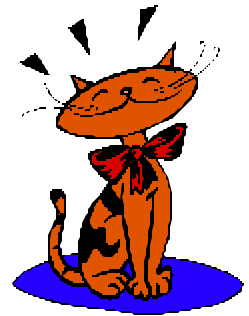
The new **and** amended lab regulations became effective on December 26, 2001. They went through three public hearings before the Board of Human Resources approved them and sent them to the Secretary of State's office.

Although we diligently sought a perfect document, we discovered a small number of typographical and formatting errors. We will send an errata sheet out with the regulations. Please review the synopsis sheet for new or amended regulations.

Some of the major changes include clarification of the definition of a clinical laboratory and laboratory test, changes in requirements for Point of Care Testing including location & turn-around time, and the addition of specific regulations for Immunohematology, Tissue Banking, Assisted Reproductive Testing, Histocompatibility, & Flow Cytometry. There was a renovation of Cytopathology and addition of specific requirements for personnel in cytology and in histology.

The Diagnostic Services Unit (DSU) staff will conduct a series of meetings around the state to clarify and elaborate on all the changes made this past year. Let us know if you are willing to provide

space at your facility for a meeting. If you have a burning question before the meetings can go forth, please do not hesitate to call or write us. We will be pleased to talk with you regarding your questions.



Georgia to Join in CLIA Waived Project

Beginning in May, 2002, Georgia surveyors will participate in the CLIA Waived Project for the Center for Medicare and Medicaid Services [CMS]. A pilot study initiated two years ago by CMS found significant quality and certification problems in over 50 percent of the labs holding Certificates of Waiver (COW). Problems included the fol-

lowing:

- ? 32 percent failed to have current manufacturer's instructions;
- ? 16 percent failed to follow current manufacturer's instructions;
- ? 32 percent did not perform quality control as required by manufacturers or the CDC. Due to the steady increase

"Significant quality and certification problems were identified in over 50 percent of the COW laboratories inspected."

in the number and types of tests waived, the expanding number of labs with no oversight, and the significant findings in COW labs, each state will be visiting two percent of the COW labs. We will be distributing good laboratory practice information. The process will be educational, helpful and emphatic, as necessary. The office will choose a random sample of different types of waived facilities such as nursing homes, pharmacies, physician offices, etc. Stay tuned for updates.

Lab Advisory Council

The official name of the "Council" is the Clinical Laboratory, Blood Bank, and Tissue Bank Advisory Committee. Its existence was mandated by the Clinical Laboratory Licensure Law of 1970 (O.C.G.A. § 31-22-3). The Council is one of the longest running and continuously active committees in

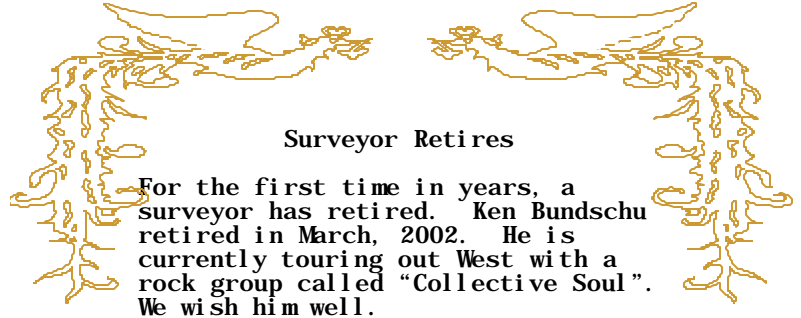
state government. There are seven members required by the law and each appointed term is for three years. The terms are staggered so that not all of the members terms expire at the same time. The member makeup is a physician, pathologist, technician, sitting administrator, chemist and last, but not least, a microbiologist.

The committee meets every other month on the second Thursday of that month. They meet in January, March, May, July, September, and November. These meetings are open to the public. Currently, the Council meets at the Public Health Lab on Clairmont Road near the VA hospital.

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Surveyor Retires

For the first time in years, a surveyor has retired. Ken Bundschu retired in March, 2002. He is currently touring out West with a rock group called "Collective Soul". We wish him well.

*Protecting Public Health and Safety Through
Regulatory Oversight*

Don't forget to e-mail us your e-mail address. Send it to:
bjlogan@dhr.state.ga.us

Meet the dsu lab staff

Jeannie Arnold

Jeannie has been with the Diagnostic Services Unit since 1991. She came to us from Rockdale County Hospital in Conyers.

Jeannie graduated from Berry College with a BS degree in Medical Technology and completed her internship at St. Joseph's Infirmary School of Medical Technology. She held the position of Chief Technologist at St. Joseph's Infirmary for ten

years and was assistant chief at Hughes Spalding for several years. Jeannie was chief tech at Rockdale Hospital for ten years. She has TNTC years of laboratory experience and is certified as an MT(ASCP).

Jeannie is a bundle of energy (we suspect the diet coke) and does more than just surveys. She does the scheduling of surveys for other staff, handles director license applications and renewals plus her quota of surveys.

On a personal note, Jeannie is now the grandmother of four, three girls and a boy. She enjoys reading, swimming and work. In between, she pampers her dogs Caesar and Cleopatra and occasionally has time to pat her husband of many years, Rick, on the head as she whizzes past him.

